UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

October 12, 2000

MEMORANDUM:

Subject: Efficacy Review of EPA Reg. No. 1043-92 "LpHse"
DP Barcode 266629
Case No. 029243

From: Nancy Whyte, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward /Portia Jenkins NOW
Product Management Team No. 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

Thru: Emily Mitchell, M.S., Team Leader Emily Mitchell 10/24/00
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: STERIS Corporation
PO Box 147
St. Louis, MO 63166-0147

Formulation Label:

	% by wt.
Active Ingredient(s)	
o-Phenylphenol	7.7%
p-tertiary-Amylpheno	7.6%
Inert Ingredients	84.7%
Total	100.000%

I. Background:

The registrant has submitted an efficacy study to support the addition of directions to the label for a 14-day holding period of a user-prepared 1:256 dilution of the purchased product This product is a one-step germicidal cleaner and microbiocide for industrial and institutional use on hard, non-porous surfaces in industrial and institutional settings only. It is sold as a concentrate. The efficacy study to support the label claim was submitted in a one-volume document (MRID No. 450996-01)

II. Use Directions:

The product comes packaged as a concentrate in a twin-neck dispensing bottle. By squeezing the bottle, the correct amount (½ ounce/15 cc) of the concentrated product enters the empty measuring chamber from the dispensing chamber. It may then be poured into one gallon of water (either hard or soft water), forming a 1:256 dilution. When stored in a closed container such as a spray bottle, it may be held for up to 14 days without loss of efficacy. The recommended contact time is 10 minutes to kill all organisms. The contact time may be reduced to kill HIV-1/AIDS virus, but the longer time is recommended for the other viruses claimed on the label. Blood and body fluids should be removed from surfaces prior to treatment for disinfection.

II. Agency Standards for Proposed Claims:

The Agency requirements for liquid products used as disinfectants are listed in DIS-TSS-01. This requires that products be tested for effectiveness using the Association of Analytical Chemists Use Dilution method or the AOAC Germicidal Spray Product Test. These tests specify that initial testing be done on three samples of the product, one at least 60 days old, against 60 carriers for *Salmonella cholerasuis, Staphylococcus aureus*, and for hospital use, *Pseudomonas aeruginosa.* Additional claims for effectiveness against other organisms for which label claims are made require testing 10 carriers each with two samples of product (total of 20 carriers for each organism). Since this is not a new registration, this product would need only confirmatory testing to support additional label claims.

IV. Summary of the Submitted Study:

The efficacy study to demonstrate the effectiveness of the product after a 14-day holding period was conducted by Hill Top Research, Inc., Miamiville, Ohio on December 29-31, 1999 and January 12-17, 2000. The study was conducted using Good Laboratory Practices(GLP) and both a GLP statement and a Quality Assurance statement is included in the documentation. Two batches of the product, Lot Nos. 220619 and 220621, each 14 and 28 days-old and diluted 1:256 in 400 ppm hard water by the registrant, were used for testing. The methodology was that of the *Official Methods of Analysis of the AOAC*, 15th ed., 1990, Chapter 5, Sec, 964.02-Disinfectants, Use-Dilution Method. An organic soil load of 4.92% horse serum was used to test the 14-day samples. A 5% organic soil load, also horse serum, was used in testing the 28 day-old solutions. Ten carriers for each organism, *Salmonella choleraesuis,* ATCC 10798, *Pseudomonas aeruginosa,* ATCC 15442, and *Staphylococcus aureus,* ATCC 6538, were exposed to the four samples of the diluted product for 10 minutes at 20° C. and incubated for approximately 48 hours to determine growth. Results showed that both the 14

day-old and the 28 day-old samples of Lot No. 220619 were effective against all carriers of all three organisms, but only the 14-day old sample of Lot No. 220621 demonstrated effectiveness against all carriers of the three organisms. One carrier of *Pseudomonas aeruginosa,* ATCC 15442 showed growth after treatment of the 28 day-old sample of Lot No. 22621. The carriers of the other two organisms showed no growth (20 carriers total).

VI. Conclusions and Recommendations:

1. A 14-day old sample of Lot No. 220619 and a 14 day-old sample of Lot No. 220621, both diluted 1:256, demonstrated effectiveness of the product against *Staphylococcus aureus,* ATCC 6538, *Salmonella choleraesuis,* ATCC`10708, and *Pseudomonas aeruginosa,* ATCC 15442 in the presence of organic soil and when diluted in 400 ppm Hard Water.

2. The request of the registrant for an amendment to add use directions on the label for the use of a 14 day-old dilution of 1:256 of the product is approved.

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division
DP Barcode: D266628 Reg. No. or File Symbol: 1043-92

Manufacturing-Use [ ] or End-Use Product [X] Case #

TO: Adam Heyward/Portia Jenkins
PM Team No. 34

FROM: Anna Skapars, Chemist
Chemistry-Toxicology Team (CTT)
Product Science Branch (PSB)

THRU: Karen Hicks, Team Leader
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Product Science Branch (PSB)

7/7/00

THRU: Michele E. Wingfield, Branch Chief
Product Science Branch (PSB)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

BACKGROUND:

The registrant is proposing to amend registration of this product by adding to the label directions for a 14 day holding period for the ready-to-use product.

FINDINGS:

The registrant is submitting storage and stability data of 2 weeks for a ready-to-use diluted product.

The proposed amendment may not be accepted under the same registration number, it should be a separate registration.

The label for a ready-to-use product will be different from an end-use undiluted product and it may not be under the same registration number.